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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/581,967	06/19/2000	Bertil Abrahamsson	1103326-0624	6706

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EXAMINER
YOUNG, MICAH PAUL

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 11/01/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Offic Action Summary	Application No. 09/581,967	Applicant(s) ABRAHAMSSON ET AL.	
	Examiner Micah-Paul Young	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-10,15-19,22,24-26 and 28-35 is/are pending in the application.

4a) Of the above claim(s) 22 and 35 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-10,15-19,24-26 and 28-34 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-10,15-19,22,24-26 and 28-35 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 8 and 9 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Papers Received

Supplemental Information Disclosure Statements received 03/01/02 and 04/22/02. Amendment and Extension of Time received 6/25/02.

Notice

Amendment dated 6/25/02 amends claims 16, 22 and 26 and adds new claims 28 – 35. The amendment cancels claim 27. New claims 28 – 24 are now grouped in to group II and summarily rejected.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 22 and 35, drawn to a method for the prophylactic or therapeutic treatment of a subject suffering from diarrhea, classified in class 424, subclass 400.

II. Claims 1 – 10, 15 – 19, 24 - 34 drawn to a pharmaceutical formulation comprising an IBAT inhibitor, a carrier and a bile acid binder, and a method of treating hypercholesterolemia, classified in class 424, subclass 78.1

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions group I is drawn to treating a disorder of the intestinal system while group I is directed to treating a disorder of the circulatory system.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 1 – 10, 15 – 19, 24 – 26 and newly added 28 – 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brieaddy et al (USPN 5,723,458) in view of Hirakawa et al (USPN 5,614,220) and Spielvogel et al (USPN 5,659,027). Claims 1 – 10, 16 – 19, 24, and 28 – 33 are drawn to a pharmaceutical composition comprising and IBAT inhibitor and carrier and a bile acid binder. Claims 15, 25, 26 and 34 are drawn to a method of treating hypercholesterolemia using the composition f the invention.

Brieaddy et al teaches the IBAT inhibitor of the invention along with the motivation to use the compound to treat hypercholesterolemia. Hirakawa et al teaches a drug formulation where drugs are delivered to various parts of the intestinal tract (ileum and colon) by varying the pH. The reference suggests varying classes of drugs that can be delivered through this formulation one of them being antilipemic agents, which are used to treat hypercholesterolemia.

Spielvogel et al teaches that it is known in the art to combine hypercholesterolemic drugs with bile acid resins. The claims recite that the composition is formulated to release in the ileum, jejunum and colon of the intestinal tract. One of ordinary skill in the art would be able to, through routine experimentation, formulate the composition to release between any pH gradient. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *See* In re Aller, 220 F.2d 454 105 USPQ 233, 235 (CCPA 1955).

One of ordinary skill in the art would have been motivated to incorporate the composition of Brieaddy in combination with a bile acid binder (as taught by Spielvogel) into the formulation of Hirakawa. A skilled artisan would have been motivated to do so in order to impart an antilipemic effect onto the formulation. A skilled artisan would also have followed the suggestion of Brieaddy to lower the cholesterol of a subject in need, by incorporating the compound into a targeted release formulation of Hirakawa. It would have been obvious to one of ordinary skill in the art, at the time of the invention to combine the teachings as such with an expected result of a composition comprising an IBAT inhibitor, a carrier, and a bile acid binder. It would be expected that such a composition would be useful in treating subjects suffering from high cholesterol.

Response to Arguments

4. Applicant's arguments filed 6/25/02 have been fully considered but they are not persuasive. Applicant argues that:

a. No suggestion exist in the Brieaddy et al to suggest a targeted release

b. No suggestion exist in Hirakawa et al to suggest an IBAT inhibitor as a possible medicament

c. The combination of Brieaddy and Hirakawa would be "obvious to try" and be done in hindsight

d. Hirakawa contains no enabling disclosures for the combination of two medicaments and cannot provide for IBAT inhibitor and bile acid binder.

e. Spielvogel does not teach or suggest the composition of the invention or a targeted release formulation.

5. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the Hirakawa reference is provided to teach that targeted release in the colon

is known for antilipemic compositions. Brieaddy is provided as said agent. Brieaddy also provides the motivation to use such a composition to lower the cholesterol of a subject in need. Since a pharmaceutical formulation takes on whatever properties of the carrier formulation, Brieaddy would provide cholesterol-lowering properties to the targeted release of profile of Hirakawa. The Spielvogel reference is provided to show that hyperlipidemic agents are commonly used in combination with bile acid binders for various reasons. The teaching would extend to the compound of Brieaddy to show them in combination.

Applicant also argues that Hirakawa contains no enabling disclosures for a combination of active agents. It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. The idea of combining them flows logically from their having been individually taught in the prior art. *See* In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). The claims regarding the purpose of the bile acid binder were not elected.

In view of these arguments it is the position of the examiner that the claims as currently presented remain obviated by the prior art presented. The compound of Brieaddy in combination as suggested by Spielvogel, in the targeted delivery of Hirakawa remains obvious over the invention.

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 703-308-7005. The examiner can normally be reached on M-F 7:30am-4: 30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-7648 for regular communications and 703-746-7648 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Micah-Paul Young
Examiner
Art Unit 1615

mpy
October 31, 2002

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600